



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------------|
| 10/500,281 | 09/09/2004 | Sanford Reich | 642P003-US | 9199 |
| 42754 | 7590 | 01/09/2008 | | |
| Nields & Lemack 176 E. Main Street Suite #5 Westboro, MA 01581 | | | EXAMINER HAND, MELANIE JO | |
| | | | ART UNIT 3761 | PAPER NUMBER |
| | | | MAIL DATE 01/09/2008 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/500,281

Applicant(s)

REICH ET AL.

Examiner

Melanie J. Hand

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 12-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed September 28, 2007 have been fully considered but they are not persuasive. Applicant argues with respect to claims 1 and 2 that none of the passages cited in the rejection of claim 1 support the Office's position and thus claim 1 is not anticipated by East. This is not found persuasive. It is explained in the rejection of claim 1 that controller 10 directs fluid flow into either of paths 36,34 in response to a change in downstream hydrostatic pressure that forces one or both of the first and second valves open. The first valve provides a greater resistance to fluid flow, thus the fluid, taking the path of least resistance, will flow through the second conduit through only the second valve, i.e. the first drainage path. A greater downstream pressure arises when siphoning occurs and is sufficient to force the first valve open, defining the second drainage path. The passage in Col. 1 is connecting this siphoning in the second drainage path with the change in elevation of the inlet with respect to the outlet of the device, which occurs when the user is upright, causing overdrainage, a problem that does not occur when the user is supine. The path of least resistance taught by East is the first drainage path, and anticipates the claimed second drainage path, also disclosed by applicant as a path of least resistance that occurs when the user is supine. Thus the controller 10, though passively, does direct the flow of fluid into either the first or second drainage path depending upon the force of the fluid flow, which is dictated by the angle of inclination of the individual.

Applicant further argues with respect to claim 3 that the siphon control device of East is downstream of valves 26 and 28 and thus is part of both conduits. Further applicant argues that anti-siphon device 30 is active regardless of the position of the user. As stated *supra*, the controller, though passively, directs the fluid into the second drainage path because controller

10 includes valves 26 and 28, wherein first valve 26 only opens when the force is sufficient because it provides a greater resistance to fluid flow than second valve 28. When a user is upright, the fluid flow necessarily has a greater inherent force as fluid flow is aided by gravity. Thus the device of East anticipates claim 3 and does in fact direct fluid flow into an upright flow path when the user's inclination is vertical or substantially vertical.

2. Applicants' arguments with regard to dependent claims 1-11 have been fully considered but are not persuasive as Applicants' arguments depend entirely on Applicants' arguments regarding the rejection of claim 1, which have been addressed *supra*.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-3, 6 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by East et al (U.S. Patent No. 5,167,615).

With respect to **claim 1**: East teaches a system for regulating the flow of cerebrospinal fluid from the brain of an individual comprising an implantable controller 10 adapted to be in fluid communication with said cerebrospinal fluid and having first and second drainage paths in the form of fluid conduits 36 and 34, respectively, wherein said controller 10 directs the flow of said cerebrospinal fluid into said first or second drainage paths via valves 26 and 28 in response to a change in downstream hydrostatic pressure to a negative downstream hydrostatic pressure, which occurs as a result of a siphoning of said hydrostatic pressure that arises when the user sits, stands or is otherwise held erect, i.e. the inclination of said individual. (Col. 1, lines 51-57, Col. 4, lines 60,61, Col. 5, lines 35-44)

With respect to **claim 2**: The first drainage path taught by East, conduit 36, is a supine flow path seen in Fig. 5 in that it is taught by East to be the path of least resistance to fluid flow (Col. 9, lines 5-10), which is the description given by applicant to the claimed supine flow path, calling said path the "low-resistance path" (Specification, Page 6, ¶5). The claimed individual's inclination of supine or substantially supine thereby flows inherently and necessarily from the teachings of East. Controller 10 directs the flow of said fluid into said supine flow path by occluding the flushable reservoir 32 by positioning plug 104, thereby permitting flow through second conduit 36, which allows the fluid to bypass the first normally closed valve 26.

With respect to **claim 3**: The second drainage path taught by East, conduit 34, is an upright flow path seen in Fig. 4, thereby causing the fluid to flow against gravity through first and second valves 26, 28 and wherein said controller 10 directs the flow of said fluid into said upright flow path via plug 104. The limitation "when said individual's inclination is vertical or substantially vertical" flows necessarily from East's teachings, as the siphon device 30 is activated only in this conduit 34 due to an absence of positive upstream fluid pressure that does occur in conduit 36 because the fluid is permitted to bypass the first valve 26. The siphon device activates to close the outlet passage 66 preventing drainage out of the siphon reservoir 88 where the fluid stands normally prior to release through the outlet conduit 66. East teaches that the siphoning control device 30 is put in place to prevent overdrainage that occurs when the patient sits, stands or is otherwise held erect.

With respect to **claim 6**: As explained *supra* with respect to claim 2, said supine flow path 36 comprises a passive low resistance flow path as taught by East. (Col. 9, lines 5-10)

Art Unit: 3761

With respect to **claim 11**: East teaches a controller 10 implanted in said individual further comprises: an inlet connection 12; an outlet connection 14 spaced from said inlet connection; an inlet cannula in the form of surgical tubing (not shown) with a distal and proximal end, wherein said distal end of said inlet cannula is located near the ventricle of the brain and said proximal end of said inlet cannula is connected to said inlet connection 12 of said controller; and an outlet cannula also in the form of surgical tubing (not shown) with a distal and proximal end, wherein the location of said distal end of said outlet cannula is the atrium of the heart, and said proximal end of said outlet cannula is connected to said outlet connection 14 of said controller. The limitation of the right atrium flows necessarily and inherently from the teachings of East as it is the only atrium that can receives blood from the bloodstream via the superior vena cava, and East teaches that excess CSF is drained into the bloodstream by the body regularly to regulate intraventricular pressure.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. Claim 7 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over East et al ('615).

With respect to **claim 7**: As stated supra with respect to claim 2, the passive low or least resistance path is associated with a supine position and thus the fluid flowing therethrough in said path when the patient is in a supine position is considered herein to be normal CSF pressure. Since the fluid taught by East is the same fluid claimed by applicant, CSF fluid, East is

considered hereinto be inherently teaching a maximum pressure of about 15 mm Hg. When the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions presumed to be inherent (MPEP 2112-2112.01). A prima facie case of either anticipation or obviousness has been established when the reference discloses all the limitations of a claim (in this case, a passive low resistance path for the flow of cerebrospinal fluid) except for a property or function (in the present case, a maximum intraventricular pressure) and the examiner can not determine whether or not the reference inherently possesses properties that anticipate or render obvious the claimed invention but has a basis for shifting the burden of proof to applicant, as per *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

7. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over East et al ('615) in view of Cowan, Jr. (U.S. Patent No. 6,585,677)

With respect to **claim 4**: East does not teach an inclination sensor for sensing the inclination of said individual. Cowan teaches a shunt for draining cerebrospinal fluid having a valve-gauge assembly 52 comprising an accelerometer as a movement sensor for sensing movement by the patient, such as reclining, that would change cerebrospinal fluid pressure, i.e. an inclination sensor. A controller in the form of a microprocessor is responsive to said inclination sensor. Cowan teaches that this controller's response to the data from the inclination sensor is a decision making criterium for the controller assembly 52 to determine how much CSF drainage to allow (thus preventing swelling due to excess CSF pressure or overdrainage), therefore it would be obvious to one of ordinary skill in the art to modify the device of East so as to have an

Art Unit: 3761

inclination sensor and a controller that is responsive to said inclination sensor as taught by Cowan to ensure the correct amount of CSF drainage to allow. ('677, Col. 5, lines 28-42)

With respect to **claim 5**: East teaches a bi-stable latching valve in the form of plug 104, and wherein said controller 10 directs the flow of said fluid by actuating said latching valve 104 via disk 118 to allow for fluid communication with said first or said second drainage paths 36,34, respectively.

8. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over East et al ('615) in view of Hakim (3,886,948).

With respect to **claim 8**: East teaches an anti-siphon device 30 in said second flow path that is considered herein to function as a check valve, as it closes off the path to the outlet 66 of the device when positive upstream cerebrospinal fluid pressure is too low, preventing overdrainage. ('615, Col. 8, lines 7-10)

East does not teach that this check valve 30 is a programmable variable check valve. Applicant's definition of cracking pressure is the following "For CSF to pass to the outlet, the pressure of the CSF at the inlet 50 must exceed the pressure exerted by the spring 53. The point at which this occurs is known as the cracking pressure." Thus since East does not teach a spring, East also does not teach a cracking pressure as disclosed. Hakim teaches a ventricular shunt having a variable pressure valve. The valve comprises a programmable variable check valve having a valve spring (taught by reference to U.S. Patent No. 3,188,142 to Hakim, Col. 2, lines 65-69) as the upstream end of the check valve pair taught therein (and with respect to valve 69 taught by Hakim in the instant prior art reference) in said second flow path 62. The

Art Unit: 3761

cracking pressure of said check valve is modified, as is the cracking pressure of valve 69, based on the inclination angle of said individual. (Col. 2, line 67 – Col. 3, line 5, Col. 4, lines 65-67)

Hakim teaches that this variable pressure check valve permits proper balance of the force exerted on the brain by the cerebrospinal fluid (CSF) pressure in the ventricle to prevent hydrocephalus, therefore it would be obvious to one of ordinary skill in the art to modify the device of East such that the check valve in the form of anti-siphon device 30 is programmable as taught by Hakim to permit the proper balance of force exerted on the brain by CSF pressure to prevent hydrocephalus.

With respect to **claim 9**: As taught by Hakim, the cracking pressure is continually modified by input from the sensor between the brain and skull where CSF fluid flows, sensing inclination of the individual based upon increase or decrease in fluid pressure that results from varying the degree of inclination of the individual to maintain a relatively stable intraventricular pressure for a range of inclination angles. (Col. 2, lines 61-67, Col. 3, lines 10-15) The motivation to combine the teachings of East and Hakim is stated *supra* with respect to claim 8.

With respect to **claim 10**: East meets all of the claim limitations of claim 10 and thus the limitation of a stable intraventricular pressure between 5 and -5 mm Hg flows inherently and necessarily from the teachings of East.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

Art Unit: 3761

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

December 31, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

